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Guidance for Industry and FDA Staff

Non-Clinical Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Interventional Cardiology Devices Branch
Peripheral Vascular Devices Branch
Division of Cardiovascular Devices
Office of Device Evaluation

Contains Nonbinding Recommendations

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet at http://www.fda.gov/cdrh/ode/guidance/1545.pdf or you may either send a fax request to (301) 443-8818 to receive a hard copy of the document, or send an e-mail request to GWA@CDRH.FDA.GOV to request hard or electronic copy. Please use the document number (**1545**) to identify the guidance you are requesting.

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Guidance for Industry and FDA Staff

Non-Clinical Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

Who should use this guidance?

All members of industry and FDA staff who perform or review non-clinical tests and prepare labeling of intravascular stents and their associated delivery systems should use this guidance. The terms "you" and "your" in this document refer to members of industry, also known as sponsors or applicants. The terms "we," "us," and "our" refer to FDA.

How should members of industry and FDA staff use this guidance?

Members of Industry

You should use this guidance to develop and apply non-clinical test protocols, test methods, and test reports that support the safety and effectiveness of intravascular stents and their associated delivery systems. You should also use this guidance to develop labeling for these devices.

FDA Staff

We should use this guidance to review non-clinical test protocols, test methods, data, and reports presented by sponsors in support of the safety and effectiveness of intravascular stents and their associated delivery systems. We should also refer to this guidance when we review the labeling for these devices.

What do the recommendations in this guidance mean?

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory

requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Does this guidance address the least burdensome approach to device applications?

The issues identified in this guidance document represent those that we believe should be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to follow the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at:
http://www.fda.gov/cdrh/modact/leastburdensome.html.

Does this document supersede any other documents?

This document supersedes the information on stent and delivery system testing in the draft document "Carotid Stent - Suggestions for Content of Submissions to the Food and Drug Administration in Support of Investigational Devices Exemption (IDE) Applications," issued October 1996.[1]

Definition of Terms Used in this Guidance

Intravascular Stent

Intravascular stents are also known as endovascular stents or vascular stents. This document uses the term "intravascular stent" to refer to intravascular, endovascular, and vascular stents.

An intravascular stent is a synthetic tubular structure intended for permanent implant in native or graft vasculature. The stent is designed to provide mechanical radial support after deployment; this support is meant to enhance vessel patency over the life of the device. Once the stent reaches the intended location, it is expanded by a ballon or self-expanding mechanisms defined below.

Balloon Expandable Stent

A balloon expandable stent is expanded by a balloon catheter. The diameter of the stent increases as the balloon diameter increases. The stent remains expanded after deflation of the balloon.

[1] You may access this draft document at http://www.fda.gov/cdrh/ode/974.pdf. The recommendations in the draft document are not in effect.

Self-expanding Stent

A self-expanding stent's diameter increases from its pre-deployed size to its post-deployed size in the absence of balloon inflation or other mechanical assistance. The self-expanding quality can result from material properties or geometry or both.

Stent Delivery System

A stent delivery system delivers a stent to a target site and then deploys the stent. A stent delivery system for a balloon expandable stent consists of a balloon catheter. Self-expanding stent delivery systems may or may not include a balloon.

II. Background

Intravascular stents, including balloon expandable and self-expanding stents, are class III devices whose product codes are given in the table below.

Table 1: Product Codes for Stents Addressed in this Guidance

Product Code	Device
MAF	Stent, Coronary
NIM	Stent, Carotid
NIN	Stent, Renal
NIO	Stent, Iliac
NIP	Stent, Superficial Femoral Artery

These devices require a premarket approval (PMA) application before marketing. See sections 513(a) and 515 of the Federal Food, Drug, and Cosmetic Act (the Act) and 21 CFR Part 814.

Clinical studies conducted in the United States in support of a PMA approval must be conducted under the Investigational Device Exemptions (IDE) regulation, 21 CFR Part 812. FDA believes that the intravascular stents addressed by this guidance document are significant risk devices as defined in 21 CFR 812.3(m).[2] Such studies require an FDA-approved IDE and sponsors must comply with the regulations governing institutional review boards (21 CFR Part 56) and informed consent (21 CFR Part 50).

After FDA has approved a device, clinical studies conducted in accordance with the indications in the approved PMA, including clinical design validation studies conducted in accordance with the quality systems regulation, are exempt from the investigational device exemptions (IDE) requirements. However, such studies must be performed in conformance with the regulations governing institutional review boards (21 CFR Part 56) and informed consent (21 CFR Part 50).

[2] Refer to http://www.fda.gov/oc/ohrt/irbs/devices.html#risk.

This guidance document supplements other FDA publications on PMA, PDP, and IDE applications and should not be construed as a replacement for those documents. For general information about these applications, see the CDRH Device Advice web site given below:

- PMAs (21 CFR Part 814): http://www.fda.gov/cdrh/devadvice/pma/
- PDPs (21 CFR § 814.19): http://www.fda.gov/cdrh/devadvice/pma/app_methods.html
- IDEs (21 CFR Part 812): http://www.fda.gov/cdrh/devadvice/ide/index.shtml.

This guidance also cites a number of voluntary standards, many of which are recognized by FDA. You may access a list of the FDA-recognized standards from the CDRH web site, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm. See also the guidance, **Recognition and Use of Consensus Standards**, http://www.fda.gov/cdrh/ost/guidance/321.html.

III. Scope

What devices does this document address?

This guidance document addresses self-expanding and balloon expandable extracranial intravascular stents and their associated delivery systems. The scope includes extracranial intravascular stents placed in coronary, central, or peripheral arteries and saphenous vein grafts but is not limited to stents used in these locations; other vascular indications outside of the intracranial vasculature are also included.

What devices does this document NOT address?

Non-vascular stents meant for use outside the vasculature are not included in the scope of this document. This document also does not include stents used in the intracranial vasculature. You should contact the Division of Reproductive, Abdominal, and Radiological Devices for information about biliary stents or the Division of General, Restorative, and Neurological Devices for information about non-vascular stents and stents used in the intracranial vasculature.

Some of the tests (and labeling recommendations) in this guidance are relevant to covered, drug-eluting, and biodegradable stents, and stents used to treat aneurysms or dissections. However, FDA recommends additional testing to fully characterize these devices. The Interventional Cardiology Devices Branch and the Peripheral Vascular Devices Branch are available to discuss testing for these stents and indications.

IV. Purpose

This document provides guidance on the preparation and review of non-clinical test protocols, methods, data, reports, and labeling for intravascular stents and their associated delivery systems.

Contains Nonbinding Recommendations

V. Content and Format of Test Data

What format should sponsors use to present test data?

We recommend that you present test data in a summary that includes the elements described below.

Table of Contents

You should place a table of contents at the front of the document. Each line listing in the table of contents should refer to major section titles and the page numbers where each section can be found.

Test Summaries

You should briefly describe all tests performed.

Test Data Summaries

You should include test data summaries for all tests. The summaries should contain:

- minimum measured value (min)
- maximum measured value (max)
- mean
- standard deviation of the test data (std. dev.).

Summary of Conclusions

You should summarize your conclusions as to whether the results support the safety and effectiveness of your device for each test.

You should include full test reports for all tests performed, as described below.

What information should sponsors include in test reports?

Your test reports should include the sections described below.

Test Specimen Information

Your test specimen description should include:

- number of test specimens
- size (diameter, length, or other relevant dimensions) of all test specimens
- rationale for the number of test specimens and sizes tested
- whether the specimens are representative of the finished product
- sterilization parameters and number of sterilization cycles applied to the test specimens.

Test Protocol

You should submit your test method or protocol. It should contain enough detail that an individual familiar with intravascular stent testing will be able to interpret the test results.

Protocol Deviations

You should describe any protocol deviations and their effect on the ability of the test data to support the safety and effectiveness of the device.

Test Parameters and Acceptance Criteria

You should report the test parameters and acceptance criteria that you use, including:

- an explanation of and rationale for critical test parameters
- specifications or acceptance and rejection criteria
- a rationale for the specification or acceptance and rejection criteria based on the clinical requirements of the device.

Raw Data

We recommend that you include all raw data in appendices or on a CD-ROM, or make the raw data available for our review upon request.

Test Results

You should summarize your test results and include statistical analysis when it is appropriate.

Data Analysis

You should analyze the data, including any outlying points and anomalous results, and explain whether the data meet the given acceptance criteria.

Conclusions

We recommend that you describe the conclusions drawn from the test results, and the clinical significance of the conclusions.

Should your tests have a test protocol?

Yes, you should establish protocols for all experiments or computational analyses, including acceptance criteria when applicable, before you perform the tests. Established test protocols help to ensure consistent repetition of tests and allow comparison of data between test runs.

We recommend that you present test protocols to us before conducting tests. We will review your protocol and provide comments. Our input before testing may improve your ability to demonstrate the performance characteristics of your device.

What information should test protocols contain?

Your test protocols should assess the most extreme clinical conditions that your device is likely to experience. Both device configuration and physiologic conditions affect the performance of devices in the human body. We recommend that you evaluate extreme device dimensions, tolerances, sizes, and any other important device parameters in your testing program. We also recommend that you examine the outer limits of physiologic variables such as blood pressure, vascular compliance, and anatomic types. You should clearly state all test conditions in the test protocol and support them with references to applicable literature, standards, or both.

Occasionally, the worst performing combination of device configuration and physiologic conditions occurs in the mid-range of the relevant variables. You should check for this situation when developing your protocols to ensure that you test the worst performing combination.

What if you believe a test is not applicable to your device?

The tests we are describing in this guidance are those we generally have reviewed in intravascular stent submissions and that we have considered necessary in the past to support the safety and effectiveness of these devices. However, some of the tests listed in this guidance do not apply to all intravascular stents and delivery systems. The designs or clinical indications to which these tests do apply are noted in their descriptions. We believe that each test helps to support the safety and effectiveness of intravascular stents. Each test's clinical or engineering significance is described in **Section VII**.

If you believe a test recommended in this guidance does not apply to your device, you should include a heading for the test in your test summary, followed by an explanation of why the test is not applicable. We will then be aware that you did not inadvertently omit it from your application.

Your explanation should include a rationale for why you do not think the test should be performed in order to support the safety and effectiveness of your device. Your rationale should clearly demonstrate, by reference to a Failure Modes and Effects Analysis (FMEA) or other risk analysis method, that the particular test or data set is not necessary or appropriate to support the safety and effectiveness of your device. Alternatively, you may identify measures you have taken to mitigate the risks associated with the device in the failure mode that would usually be tested using the test that you have not performed.

Intravascular stents have been in clinical use for over a decade and some designs are in their fourth or fifth generation. Some attributes may not depend on the changes made to a next-generation device. For a particular attribute, rather than providing original data for a next-generation design, it may be appropriate to reference previously tested stents in the same device family. We believe, however, that a reference to previous generic device experience, for example, "alloy X has been used in stents," generally is not adequate. If you choose to reference previously tested stents, you should explain why the previous testing is relevant.

What sample size should sponsors use for tests?

You should use a statistically significant sample size whenever possible. When using a statistically significant number of samples is not possible, you should provide a scientific rationale to support the number of samples tested in your test summary and test protocols, and provide reasonable assurance that the test results support the safety and effectiveness of the device.

Should sponsors test finished product?

All test samples should represent the finished product. Your devices should be sterilized by the final production process, including repeat sterilization cycles. You should note any tests that use samples that are not finished, sterilized product in the test summary and test protocols, and explain why doing so does not affect the ability of the test results to support the safety and effectiveness of the device.

What size devices should sponsors test?

You should test the full range of sizes that you intend to commercially distribute. The recommended default paradigm is a 2 x 2 factorial of the largest and smallest diameters and lengths, also known as the "four corners" paradigm for each different stent design. We recommend a different set of sizes for some of the tests in **Section VII. Table 2** illustrates the four corners concept for a typical coronary stent. If you do not test a device using the four corners paradigm or the recommended sizes for a particular test, you should provide a scientific rationale to support the sizes that you do test in the test summary and test protocols. For some tests, we may recommend that you perform an analysis to identify the size or sizes that represent the worst case.

Table 2: Four Corners Test Paradigm Example

Stent Diameter (mm)	**Stent Length (mm)** 8	12	18	24
2.5	X			X
3.0				
3.5				
4.0	X			X

VI. Risks to Health

FDA has identified some of the risks generally associated with the use of the intravascular stents addressed in this document. The preclinical and labeling measures recommended to address these risks are given in this guidance document. You should conduct a risk analysis to identify other risks specific to your device, and include the risk analysis in your application. The application should describe the risk analysis method. If you elect to use an alternative approach to address a particular risk identified in this document, or you have identified risks in addition to those in this document, you should provide sufficient detail to support the approach you have used to address that risk.

D. Biocompatibility

Significance

Stent and delivery systems contain patient-contacting materials, which when used for their intended purpose, i.e., contact type and duration, may induce a harmful biological response.

Recommendation

We recommend that you determine the biocompatibility of all patient-contacting materials present in your device. If your materials are identical in composition and processing methods to materials with a history of successful use in cardiovascular implant applications, you may reference the appropriate literature or previous clinical experience. We recommend that you test novel materials, i.e., those with no history of successful prior use according to the methods in the FDA-recognized version of ASTM F748 or the FDA-recognized sections of ISO 10993. We recommend that you follow the guidance **Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing**[3]

VIII. Labeling

General labeling requirements for medical devices are described in 21 CFR Part 801. Additional information may be obtained from Device Advice http://www.fda.gov/cdrh/devadvice/. You must submit all proposed labeling in your PMA. 21 CFR 814.20(b)(10).

FDA recommends that labeling for extracranial intravascular stents include the sections described below. These recommendations reflect the labeling that we have considered necessary in that past to support the safety and effectiveness of these devices and are consistent with labeling of currently marked intravascular stents. Some of these recommendations may also be relevant to covered, drug-eluting, and biodegradable stents; however, FDA recommends additional labeling, not described in this document, for those devices. The Interventional Cardiology Devices Branch and the Peripheral Vascular Devices Branch are available to discuss labeling for those stents and indications.

A. Device Description

We recommend that you describe the stent and delivery catheter, including the stent material, whether the stent is balloon expandable or self-expanding, etc. You should consider including a table with the following attributes, as appropriate:

- available stent diameters and lengths
- guiding catheter compatibility
- deployment and RBPs
- percent stent free area.

[3] http://www.fda.gov/cdrh/g951.html

Appendix A: Test Summary Checklist
(continued on next page)

Test		Sizes Tested and Sample Sizes	Test Method or Standard Reference	Accept/Reject Criteria	Results
Material Characterization	Material Composition				
	Shape Memory and Superelasticity				
	Mechanical Properties				
	Corrosion Resistance				
Stent Dimensional and Functional Attributes	Dimensional Verification				
	Percent Surface Area of the Stent				
	Foreshortening				
	Recoil for Balloon Expandable Stents				
	Stent Integrity				
	Radial Stiffness and Radial Strength				
	Stress Analysis				
	Fatigue Analysis				
	Accelerated Durability Testing				
	MRI Safety and Compatibility				
	Radiopacity				
	Coating Durability *(coated stents only)*				
	Crush Resistance (*peripheral indications only*)				
	Kink Resistance (*peripheral indications only*)				

Appendix A: Test Summary Checklist (*continued from previous page*)

Test		Sizes Tested and Sample Sizes	Test Method or Standard Reference	Accept/Reject Criteria	Results
Delivery System Dimensional and Functional Attributes	Balloon Rated Burst Pressure (*balloon expandable stents only*)				
	Balloon Fatigue (*balloon expandable stents only*)				
	Stent Diameter vs. Balloon Pressure (Compliance Chart) (*balloon expandable stents only*)				
	Catheter Bond Strength				
	Crossing Profile				
	Balloon Inflation and Deflation Time (*balloon expandable stents only*)				
	Stent Securement for Unsheathed Stents				
Biocompatibility	Biocompatibility				

Appendix B: Applicable Standards

A list of FDA-recognized standards is available at
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

ISO Standards
10993 Biological Evaluation of Medical Devices
25539-1 Cardiovascular Implants – Endovascular Devices • Part 1 – Endovascular Prostheses, Annex D – In vitro Testing and Reporting

ASTM Standards
F746 Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials
F748 Standard Practice for Selecting Generic Biological Test Methods for Materials and Devices
F2004 Standard Test Method for Determination of Transformation Temperature of Nickel-Titanium Alloys by Thermal Analysis
F2052 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Passive Implants in the Magnetic Resonance Environment
F2079 Standard Test Method for Measuring Intrinsic Elastic Recoil of Balloon expandable Stents
F2081 Standard Guide for Characterization and Presentation of the Dimensional Attributes of Vascular Stents
F2082 Standard Test Method for Determination of Transformation Temperature of Nickel-Titanium Shape Memory Alloys by Bend and Free Recovery
F2119 Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
F2129 Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices
F2182 Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging
F2213 Standard Test Method for Measurement of Magnetically Induced Torque on Passive Implants in the Magnetic Resonance Environment
G71 Standard Guide for Conducting and Evaluating Galvanic Corrosion Tests in Electrolytes

Boston Scientific

PROMUS™

Everolimus-Eluting Coronary Stent System

Patient Information Guide

A1112

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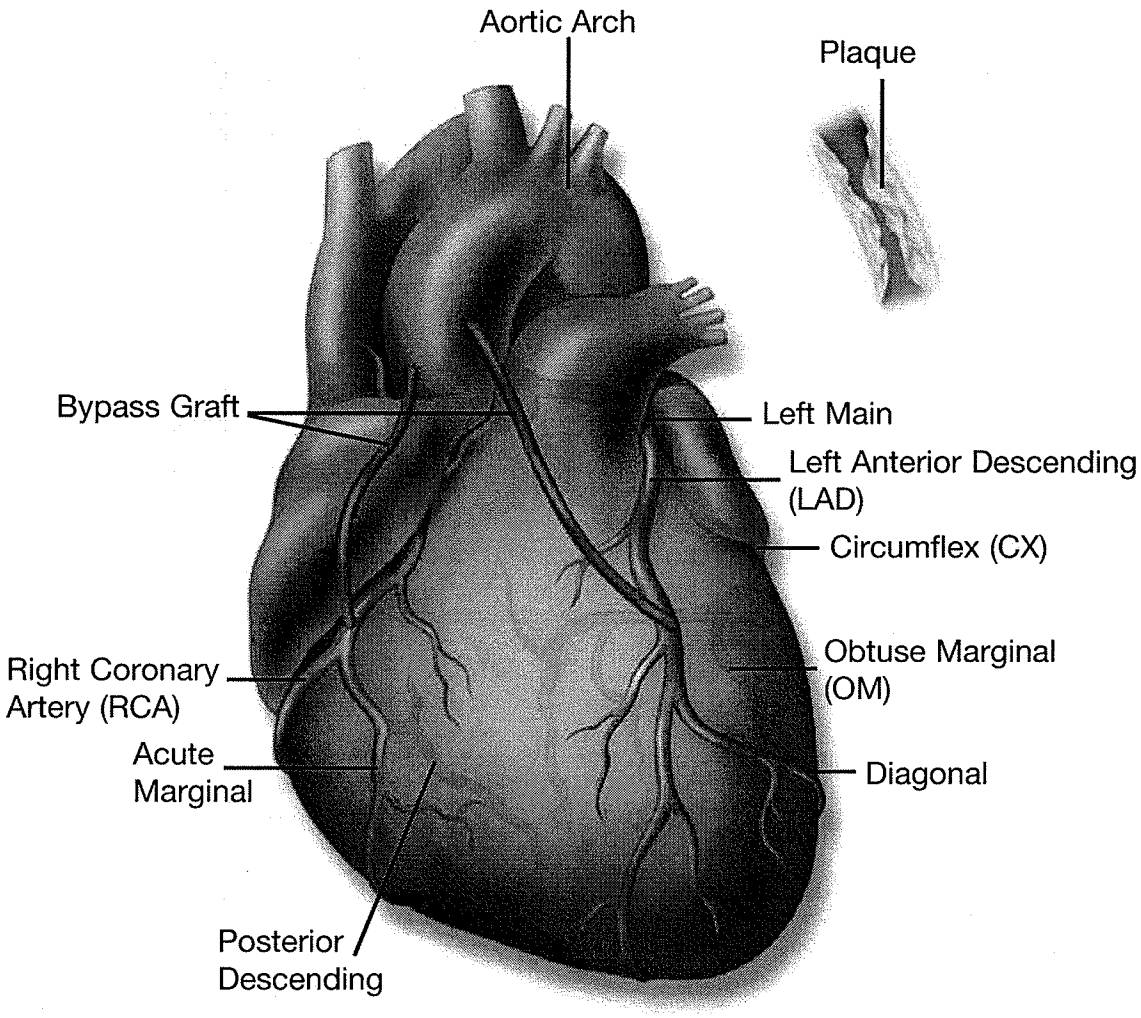
Table of Contents *(continued)*

Coronary Vasculature



Coronary Artery Disease (CAD)

Your Heart

Your heart is a muscle that pumps blood throughout your body. The blood carries oxygen and nutrients that your body needs to work correctly. For the heart to be able to function properly, it also needs a constant supply of oxygen-filled blood. The vessels that supply this blood to the heart are called coronary arteries. If these arteries become blocked or narrowed, treatment may be required to restore blood flow and the vital supply of oxygen to the heart.

What is Coronary Artery Disease (CAD)?

CAD is the most common form of heart disease. It is a condition that occurs when the arteries that supply oxygen-rich blood and nutrients to the heart muscle become narrowed or blocked by a gradual build-up of "plaque." Plaque is made up of fatty deposits (cholesterol), white blood cells, calcium, and other substances that collect over time in the wall of a coronary artery. As the plaque narrows the opening (lumen) of a coronary artery, it makes it difficult for adequate quantities of blood to flow to the heart muscle. This process is called

Coronary Artery Disease (CAD) *(continued)*

"atherosclerosis." Gradual reduction of blood flow to the heart muscle can cause chest pain (angina). A heart attack (myocardial infarction) can occur if the artery suddenly becomes completely blocked, usually by a blood clot that forms over ruptured (broken) plaque. Heart attacks cause irreversible damage to the heart muscle. The first symptom of CAD can also be sudden death.

Improved medical treatment, combined with earlier diagnosis, and increased public awareness of the symptoms and risk factors that contribute to this disease are helping to decrease the death rate from CAD.

What are the Symptoms of CAD?

Two common symptoms of CAD are chest pain, also known as angina, and shortness of breath, which are caused by the reduction of blood flow to the heart muscle. If plaque build-up does not reduce blood flow excessively, there may be no noticeable symptoms at rest, but symptoms such as heaviness in the chest may occur with increased activity or stress.

Coronary Artery Disease (CAD) *(continued)*

Other symptoms that may be experienced are:

- Pain in the jaw or neck
- Pain radiating to the arms or back
- Heartburn
- Nausea
- Vomiting
- Heavy sweating

When blood flow is significantly reduced and the heart muscle does not receive enough blood to meet its needs, severe symptoms such as chest pain (angina pectoris), heart attack (myocardial infarction), or heart rhythm disturbances (arrhythmias) may occur.

There are some patients who report no symptoms of CAD. It is possible to have a heart attack without experiencing any symptoms.

Coronary Artery Disease (CAD) *(continued)*

Recent research has shown that some women experience different CAD symptoms from men and are less likely than men to report chest pain, heaviness in the chest, or chest discomfort during a heart attack. Women may notice other early symptoms, such as unusual tiredness or sleep disturbances up to one month prior to a heart attack. These differences in symptoms may cause some women to delay seeking help or treatment.

What are the Risk Factors of CAD?

Two main risk factors for CAD are:

- Increasing age (over age 65)
- Being male or a menopausal female[1]

[1]Menopausal women begin to develop and die of heart disease at a rate equal to men. Menopause is the transition in a woman's life when production of the hormone estrogen in the body falls permanently to very low levels, the ovaries stop producing eggs, and menstrual periods stop.

Coronary Artery Disease (CAD) *(continued)*

Other risk factors that may increase your chances of developing CAD are:

- Family history of heart disease (close relatives with heart disease at a young age)
- Diabetes
- High blood cholesterol levels
- Smoking
- High blood pressure
- Stress
- Obesity (being overweight)
- High fat diet
- Lack of exercise

How Can My Doctor Tell if I Have CAD?

If your doctor suspects that you have CAD or if you have symptoms of the disease, he/she will ask you about your risk factors and your symptoms. A complete physical exam and blood tests to identify injury to your heart muscle will also be completed. In addition, some of the tests used to make the diagnosis are:

Coronary Artery Disease (CAD)
(continued)

Electrocardiogram (ECG/EKG) is a commonly used test that records your heart's electrical activity and can show certain problems such as abnormal heartbeats or damage to the heart muscle. An ECG can be done at rest or while you are walking or running on a treadmill or pedaling a stationary bicycle (Stress ECG).

Stress Tests are used to evaluate your heart rate, heart rhythm, and ECG while you are exercising. The results of a stress test can help your doctor determine the areas of heart muscle which are affected by lack of blood flow due to CAD.

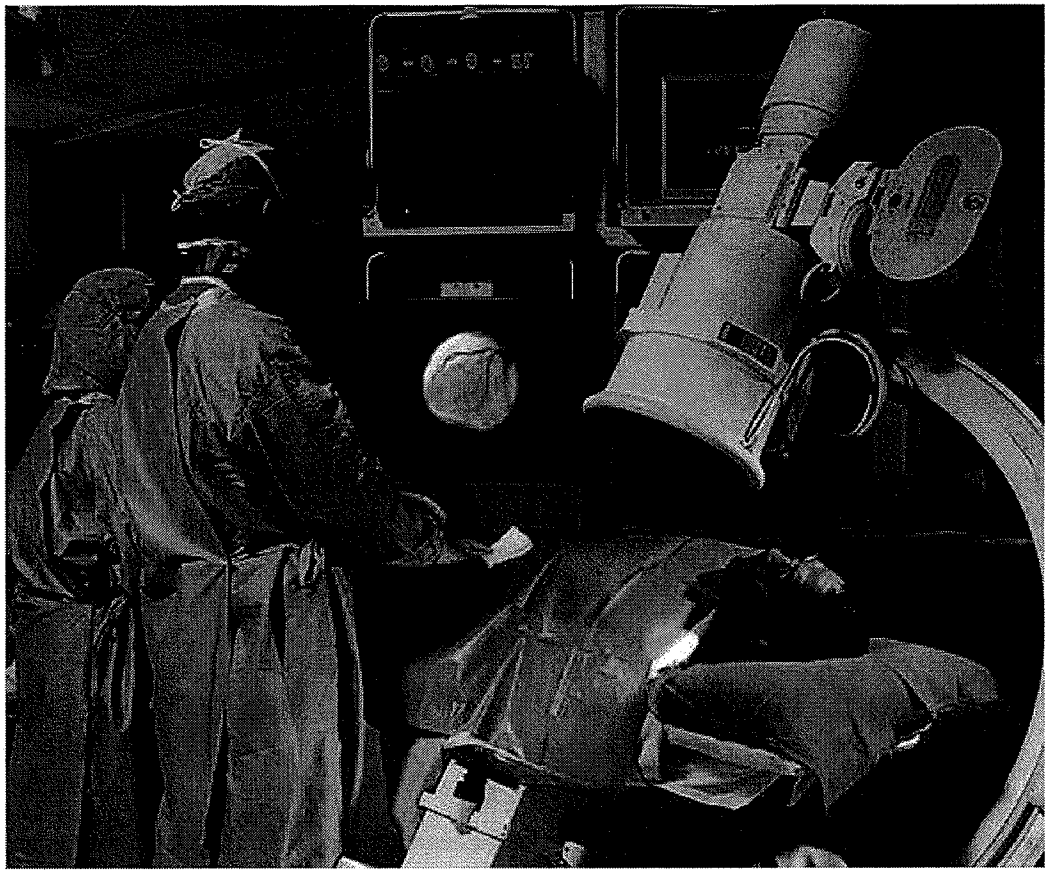
Echocardiography is an exam of the heart using sound waves.

Coronary Angiogram or Heart Catheterization is a procedure carried out in the cardiac catheterization laboratory (cath lab) by a cardiologist. Angiography is a procedure in which coronary arteries are visualized using X-rays.

Coronary Artery Disease (CAD) *(continued)*

A catheter (long, thin, hollow tube) is inserted into an artery in the groin or arm. The tip of this tube is positioned at the beginning of the arteries supplying blood to the heart, and a special fluid called contrast dye is injected through the tube to visualize the blood vessels on X-rays so that pictures, called angiograms, can be taken. These angiograms allow the doctor to see any blockage and/or narrowings in your coronary arteries and determine their severity.

Using the information gathered from one or more of these tests, your doctor is better able to decide the best treatment plan for you.



Cardiac Catheterization Laboratory

Your Treatment Options

Once a diagnosis has been made, your doctor will recommend the most appropriate form of treatment, depending on the condition and severity of your CAD. CAD can be managed by a combination of changes in lifestyle (eating a healthy, low-saturated fat diet, regular exercise, and quitting smoking) and medical treatment. Your treatment may include medications to relieve your chest pain and/or to expand the coronary arteries, increasing blood flow to your heart.

However, because medicine alone may not clear blocked arteries, you may need more treatment, including surgery, angioplasty, and/or stenting to treat your symptoms.

Your doctor will explain the risks and benefits of your treatment options and answer any questions you or your family may have. You are encouraged to discuss your treatment options with your doctor.

Your Treatment Options *(continued)*

Surgery

Coronary artery bypass grafting is a common surgical procedure that removes a section of artery or vein from another part of your body. This vessel is then connected (grafted) to the coronary artery at the blockage site. This creates a new path for blood to flow around (bypass) the blocked artery and to your heart. Often, several blocked arteries are bypassed during the same operation. Most coronary bypass patients remain in the hospital for about a week, followed by a recovery period at home.

Angioplasty

Angioplasty is a procedure used to open blocked arteries. You may also hear it referred to as PTCA (Percutaneous Transluminal Coronary Angioplasty). This procedure is performed under local anesthetic in a cardiac catheterization laboratory. A catheter with a small balloon mounted on the end is passed into the coronary artery. The catheter is then positioned at the narrowed portion of the artery and the balloon is inflated. As the balloon inflates, it pushes out against the wall of the coronary artery and compresses the plaque. The balloon is then deflated and the catheter

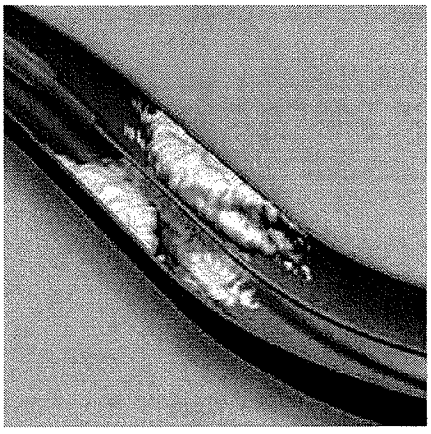
Your Treatment Options *(continued)*

is removed from the artery. This opens the narrowing in the coronary artery and improves the blood flow to the heart muscle. In balloon angioplasty, no permanent device remains in the artery after the balloon catheter is removed. Balloon angioplasty can be performed with a balloon alone or can involve placement of a permanent device called a stent, within the coronary artery.

Although balloon angioplasty enlarges the lumen of coronary arteries, many patients develop re-narrowing of the vessel in the months following the procedure. This process is called restenosis, and it is caused by the growth of scar tissue within the coronary artery.

Step 1:

The doctor guides a catheter with a small balloon through the blood vessel to the narrowed section of the artery. By watching the progress of this catheter on the fluoroscope (an X-ray device that creates real-time images



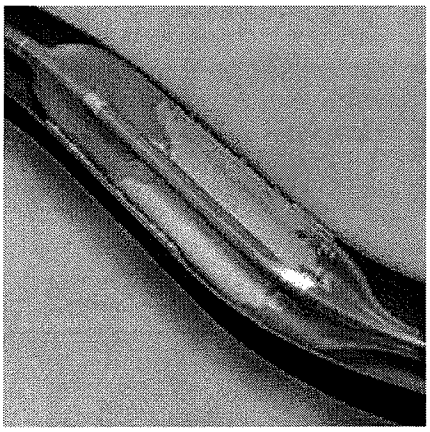
Step 1

Your Treatment Options *(continued)*

of the internal structures of the body that can be viewed on a TV monitor), the doctor is able to maneuver it into the blocked coronary artery.

Step 2:

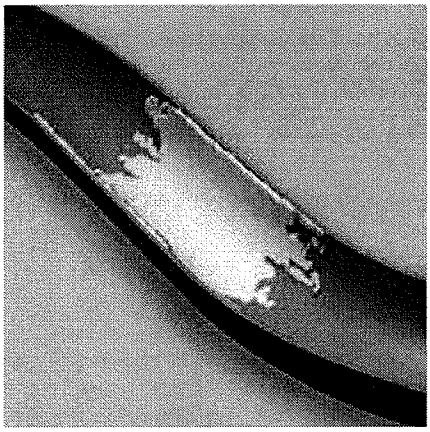
The balloon is inflated, pushing out against the wall of the artery and compressing the plaque. The balloon is deflated and the catheter is removed.



Step 2

Step 3:

The inside of the blood vessel is now larger and the blood flow is improved.



Step 3

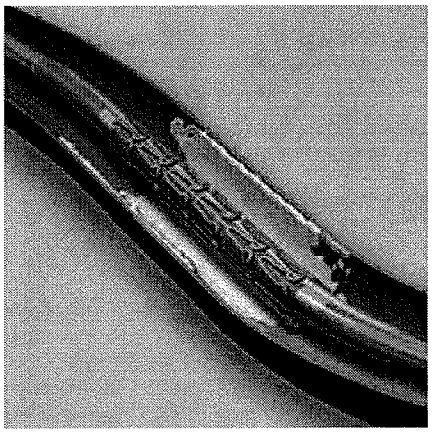
Your Treatment Options *(continued)*

Coronary Artery Stents

Coronary artery stents are devices (small metallic mesh tubes) that are placed over a balloon catheter and delivered to the narrowed portion of the coronary artery. The balloon is used to expand the stent. The stent presses against the narrowed vessel wall holding the vessel open. This makes a wider channel to improve blood flow to the heart muscle. This may be followed by repeat balloon inflations within the stent to achieve the result desired by your doctor. Once the balloon has been deflated and withdrawn, the stent stays in place permanently, holding the coronary artery open. The inner lining of the artery grows over the surface of the stent, making the stent a permanent part of your artery.

Step 1:

The doctor maneuvers the catheter into the blocked artery and inflates the balloon.



Step 1